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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,542	09/29/2006	Gary H. Graetz	11398.72.1a.4	1533
22913	7590	03/30/2009	EXAMINER	
Workman Nydegger 1000 Eagle Gate Tower 60 East South Temple Salt Lake City, UT 84111			KIM, SUN U	
			ART UNIT	PAPER NUMBER
			1797	
			MAIL DATE	DELIVERY MODE
			03/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,542	Applicant(s) GRAETZ ET AL.	
	Examiner JOHN KIM	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-51 is/are pending in the application.
- 4a) Of the above claim(s) 46-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/22/07, 1/8/08, 2/1/08</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 40-45, drawn to a disposable pooling assembly, classified in class 422, subclass 101.
 - II. Claims 46-51, drawn to a method for pooling a fluid solution, classified in class 210, subclass 767.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used without mixing fluid in the compartment or delivering fluid out to a filter out of compartment of bag.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

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(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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4. During a telephone conversation with Mr. Dana Tangren on 3/17/09 a provisional election was made with traverse to prosecute the invention of Group I, claims 40-45.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 46-51 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 40-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Kern (US Patent No. 5,362,642).

Regarding claim 40, Kern teaches a disposable pooling bag assembly comprising a flexible pooling bag (8) bounding a compartment (12, 14), the pooling bag (8) having an inlet port (22) and an outlet port (18) communicating with the compartment (12, 14), a filter (40) in fluid communication with the inlet port (22) of the pooling bag (10) and a circulation line (52, 56, 58) projecting outside of the compartment (14) of the pooling bag (8) and having opposing ends in fluid communication with the compartment (14) of the pooling bag

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(8), wherein the flexible pooling bag (8), the filter (40) and the circulation line (52, 56, 58) are sterilizable (see figure 1; col. 7, line 65 – col. 12, line 53). The recitation of “the flexible pooling bag, the filter and the circulation line are concurrently sterilized as a preassembled, closed system” is not given patentable weight in the apparatus claim as this recitation is an intended use.

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Regarding claim 41, Kern teaches that the compartment of the pooling bag has a volume of at least 500 liters e.g. 800-1,200 liter size (see col. 8, lines 23-25).

Regarding claim 42, Kern teaches that the filter (40) has a filter membrane with a porosity of 0.2 micron (see col. 10, lines 22-24).

Regarding claim 43, Kern teaches a dip tube (60) at least partially disposed within the compartment of the pooling bag (8) and being in fluid communication with the circulation line (52, 56, 58) (see figure 1; col. 11, lines 42-59; col. 12, lines 7-13).

Regarding claim 44, Kern teaches that a peristaltic pump (24) coupled with the circulation line((52, 54, 58) outside of the compartment (14) of the pooling bag (8) (see figure 1; col. 9, lines 45-59).

Regarding claim 45, Kern teaches that an elongated fluid line (62) in fluid communication with the outlet port (18) on the pooling bag (8), the fluid line (62) being sterilizable (see figure 1). The recitation of “the fluid line being concurrently sterilized with the pooling bag” is not given patentable weight in the apparatus claim as this recitation is an

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intended use. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent No. 3,710,454 and 6,251,295 and 5,403,272 and 7,264,608 teach a pooling assembly.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN KIM whose telephone number is (571)272-1142. The examiner can normally be reached on Monday-Friday 7 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/John Kim/

Primary Examiner, Art Unit 1797

JK

3/19/09